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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,631	01/06/2006	Sampad Bhattacharya	1438-15	1898

24106 7590 05/12/2008
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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,631	BHATTACHARYA ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 40* is/are pending in the application.

4a) Of the above claim(s) *20 - 22, 41 - 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 19, 23 - 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I in the reply filed on March 26, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant did not elect whether the optional functional coat was present. To further prosecution of the Application, the Examiner has interpreted this as the presence of the optional coat is not required. Accordingly, claims 20 – 22 have also been withdrawn from consideration.

Specification

2. The disclosure is objected to because of the following informalities: in paragraph [0016], the temperature is indicated as "37 ?C".

Appropriate correction is required.

3. The disclosure is objected to because of the use of trademarks. The use of the trademarks "Eudragit", "Surelease" and "Aquacoat" has been noted in this application.

It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

4. Claim 32 is objected to because of the following informalities: an apparent typographical error in the word "polising" is present. Appropriate correction is required.

5. Claim 39 is objected to because of the following informalities: an apparent typographical error in the word "formulaation" is present. Appropriate correction is required.

6. Claim 24 is objected to because of the following informalities: a claim can only be one sentence in length and therefore can only contain one period Lines 6 and 11 both contain periods. Appropriate correction is required.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1 – 14, 16 – 19, and 23 – 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 7 of copending Application No. 11/031,266. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1 – 7 of '266 are generic to all that is recited in the cited claims of the instant application. That is, the claims of the instant application fall entirely within the scope of claims 1 – 7 of '266. Specifically, the claim of '266 recite an extended releases formulation of venlafaxine with mini tablets comprised of a core containing venlafaxine, microcrystalline cellulose (a diluent) and polyvinylpyrrolidone (a binder) and an outer coating of a water insoluble and water soluble polymer. The claims of the instant application recite an extended release venlafaxine formulation with a particulate phase (core) comprised of venlafaxine, and at least one osmogen/osmotic agent or osmopolymer, a diluent, a binder and a hydrophobic polymer membrane with a coating comprised of a hydrophilic (water-soluble) polymer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112 1st Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 8, 10, 14, 27 – 26 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims contain the items "other similar or equivalent materials" or "and the like materials". Applicant has provided no information as to how similar or alike members of this class must be in order to be a member of the Markush claim that concludes with one of the two cited phrase. As the compounds listed a diverse in structure and can encompass a myriad of possibilities, "other similar or equivalent materials" and "and the like materials do not meet the written description provision of 35 USC § 112, first paragraph

Claim Rejections - 35 USC § 112 2nd Paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1 – 19 and 23 – 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. The limitations on the inner solid osmo-microsealed phases in claim 1 contains the phrase "and at least one osmogen/osmotic agent or osmo polymer, a diluent, a binder and a hydrophobic polymer membrane forming the core". It would appear that one must select at least one osmogen or osmo polymer and all the other ingredients are required. However, dependent claims used the words "further comprising" in conjunction with the items included in the list, followed by amounts. So it is unclear whether the list in claims 1 is an improper Markush group and the further comprising language in the dependent claims 4, 7, 9, and 12 is directed toward requiring one item from the Markush group in a particular amount or if the presence of all the items in the list in claim 1 is required and the dependent claims are simply limiting the amount of the ingredient that may be present.

13. Claims 1 – 19 and 23 – 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The inner particulate phase is comprised of "venlafaxine Active or salt thereof". It is unclear what "venlafaxine Active" is and how this compound differs from venlafaxine.

14. Claims 1 – 19 and 23 – 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These are composition claims but the independent claim contains an active step – "compressed into tablets". The patentability

of product-by-process claims is determined by the product (see MPEP 2113). This claim has been treated a product claim in which the pharmaceutical formulation is a tablet for the purposes of applying art below.

15. Claims 2 – 4, 7, 9, 11, 12, 15, 16, 18 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "preferably" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, these claims recite the broad ranges for the amount of an ingredient that is present and then the claims recite a preferred, narrowed range.

16. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A ratio between the inner osmo microsealed particulate phase is presented. However, the quantities used to calculate the ratio (volume or mass of the layers, for example) is not defined.

17. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In this claim, the presence of a specialty binder is excluded. The specification does list compounds that are binders and the claim states that binding by diluents such as lactose is sufficient so lactose is not a specialty binder. However, what binders are specialty binders or what properties make a binder special are not defined by the claims or the specification. Therefore, the identity of the compounds being excluded from the composition is not defined so an artisan of skill in the art would not know which compounds applicant envisioned excluding at the time of filing as set forth in the claim.

18. Claims 8, 10, 14, 27 – 36 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these claims contains a Markush grouping that contains the limitation "other similar or equivalent materials" or "the like materials". A Markush group is a closed list from which one (or more) item is selected. However, in these claims the members of the group from which items are

selected cannot be determined because this broad, undefined category is included in the Markush group.

19. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Many of the items listed are narrower and even narrower limitations of items listed previously so it is unclear what items must be present. The first two items on the list, organic and inorganic compounds, all compounds. For example, the term salt and sodium chloride are both present in the list. It is therefor unclear if any compound can be present, if a salt must be present or if a specific salt must be present. The item "other similar or equivalent materials" only adds the indefiniteness of this claim.

20. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, a hydrophobic water soluble and/or swellable polymer is required in the outer solid continuous phase. Claims 16 states that this layer "further comprised of hydrophilic polymers in an amount...". It is unclear whether this claim is requiring the presence of an ingredient that is already present or is refining that amount of that ingredient present in the layer.

21. Claims 16, 18, 26 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is insufficient antecedent basis for the limitation of "dosage form/tablet" in the claim as the independent claim only refers to a tablet or formulation and not a dosage form.

22. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim contains the trademark/trade name CARBOPOL. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe carbomers and, accordingly, the identification/description is indefinite.

23. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. The amount of ingredients present in the composition is defined as “a recommended level”. Who or what is recommending the level and/or what those levels are is not defined in the claims or the specification. Therefore, the metes and bounds of the claims cannot be determined because what levels are “recommended” is not defined.

24. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 recites the limitation "the coats of inner particulate phase" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

25. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "such plasticizers can also include" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Many of the items listed are narrower and narrower limitations of items listed previously so it is unclear what items must be present. This list also include duplicate items such as the first two items: “low molecular wt polymers” and “low molecular weight polymers”. Low molecular weight polymers, copolymers, multi-block polymers are all broad but overlapping groups, while a number of specific compounds are also listed.

26. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether fatty acids and fatty acids esters is part of the classification of oil as neither fatty acids nor fatty acid esters is not listed in claim 24 and therefore lack antecedent basis unless they are included as part of the classification "oils". The format of the claim seems to indicate that fatty acids and fatty acid esters are not part of the category "oils".

27. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether Applicant has presented an improper Markush group of items or if all eleven components listed must be present in the composition of claim 1. For example, the inclusion of an acidifying agent, an alkalizing agent would generally offset each other. It is also unclear if these components must be present in a particular portion of the formulation or must simply be present somewhere in the composition.

28. Claims 31 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "such as" and "the like materials" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

29. Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In both of these claims is unclear whether an improper Markush group has been presented or if the surface active and soap in claims 38 and 39 respectively comprise multiple components or at least one is selected from the group. In claim 39, the identity of the items listed is also unclear and whether Applicant means fatty acid alkali metal salts, fatty acid ammonium salts and triethanolamine or if the list should be ammonium; triethanolamine salts; and a fatty acid alkali metal.

30. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

31. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

32. Claims 1, 2, 4 – 6, 9, 10, 12 – 14, 16 – 19, 23, 24 and 26 – 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Faour et al. (PGPub 2001/0048943).

Faour et al. discloses an osmotic device containing venlafaxine (paragraph [0001]). The core can comprise the active ingredient and at least one osmotic agent or osmopolymer and a semipermeable membrane surrounding the core.

In example 1, the core is comprised of venlafaxine hydrochloride, the diluent mannitol, the binder povidone are present in amounts, in weight percentage based only on the weight on the core, of 22%, 63% and 6.6% respectively for the 37.5 mg formulation (paragraph [0100]). These ingredients were granulated to form particles (paragraph [0096]). Several coating layers were applied, including a layer comprised of hydroxypropyl methyl cellulose, a hydrophilic water swellable polymer (paragraph [0100]). In example 1, the ratio of the mass of the ingredient core to the mass of all of the coating layers was 3.8:1. Additional fillers and excipients such as polyethylene glycol are present in the coating layer (paragraph [0100]). Polyethyleneglycol 400 and 600, low molecular weight poly(ethylene glycol) are present in this formulation and can function as plasticizers. Also present are magnesium stearate (an antiadherant and lubricant), titanium dioxide (opaquant), colloidal silicon dioxide (glidant) and the colorants Aluminum Lake Quinoline Yellow and Aluminum Lake Sunset Yellow.

Claim Rejections - 35 USC § 103

33. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

34. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

35. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

36. Claims 1, 3, 7, 8, 10, 25 and 31 – 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al. (PGPub 2001/0048943).

Faour et al. discloses an osmotic device containing venlafaxine (paragraph [0001]). The core can comprise the active ingredient and at least one osmotic agent or osmopolymer and a semipermeable membrane surrounding the core.

In example 1, the core is comprised of venlafaxine hydrochloride, the diluent mannitol and the binder povidone (paragraph [0100]). These ingredients were granulated to form particles (paragraph [0096]). Several coating layers were applied, including a layer comprised of hydroxypropyl methyl cellulose, a hydrophilic water swellable polymer (paragraph [0100]). Additional fillers and excipients such as polyethylene glycol are present in the coating layer (paragraph [0100]). Polyethyleneglycol 400 and 600, low molecular weight poly(ethylene glycol) are present in this formulation and can function as plasticizers. Also present are magnesium stearate (an antiadherent and lubricant), titanium dioxide (opaquant), colloidal silicon dioxide (glidant) and the colorants Aluminum Lake Quinoline Yellow and Aluminum Lake Sunset Yellow.

Faour et al. also discloses the presence of osmotically effective solutes, osmotic agents or osmagents when the tablet is an osmotic device (paragraph [0053]). The composition can also comprise acidifying agents, alkalizing agents, antioxidants, buffering agents, colorants, tablet antiadherenta, tablet binders, tablet and capsule diluents, tablet glidants, tablet lubricants, tablet or capsule opaquans and/or tablet polishing agents (paragraph [0054]). Specific examples of ingredients in each of these

categories are also presented (paragraphs [0055] – [0071]). The tablets can also employ one or more surface active agents (surfactants) that improve wetting or disintegration of the tablet core or layers (paragraph [0073]). Examples given include soaps, synthetic detergents including cationic detergents and fatty acid alkali metal, ammonium and triethanolamine salts (paragraph [0077]). Plasticizers (paragraph [0075]) and oils (paragraph [0076) can also be included in the formulation.

Suggested amounts of some of the various classes of ingredient are presented in paragraphs [0110] and [0111].

Faour et al. does not prepare an exemplary composition in which all of the ingredients are present.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to prepare an osmotic tablet formulation of venlafaxine with a variety of excipients present as Faour et al. clearly discloses but does not prepare such compositions. The specific amounts of these components in a results effective parameter which an artisan of ordinary skill in the art would routinely optimize in order to achieve the desired parameters for the dosage formulation.

37. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al. and further in view of Patel et al. (US 6,248,363).

As discussed above, Faour et al. disclose an osmotic controlled release formulation of venlafaxine.

Faour et al. does not describe the dimensions of the particles.

Patel et al. discloses that typical size of solid carriers for pharmaceutical active ingredients is typically less than about 2 mm easily passes through the stomach and is therefore is less prone to gastric emptying variability (col 1, ln 57 – 63). For granulation, the process employed by Faour et al., the size and size distribution of the pellets can be adjusted by ingredients and processing conditions (col 46, ln 57 – 62).

It would have been obvious to one of ordinary skill to prepare a venlafaxine formulation as taught by Faour et al. with a particle size of 2 mm or less and to adjust that size by adjusting a variety of parameters as Patel et al. teaches that solid carriers of that size result is less variability delivery to the small intestine.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW